K123826

FEB 14 2013

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

Proprietary Name	Vitro Molar
Date Prepared	December 4, 2012
Submitter	DFL Industria E Comercio S.A. Estrada do Guerengue, 2059-Jacarepagua Rio de Janerio-RJ-Brazil CEP 22713-002
Official Contact	Tara Conrad TechLink International Consulting 18851 NE 29th Avenue Suite 720 Aventura, FL 33180 TEL- (305) 377-0077 FAX- (305) 377-0088
Common Name	Dental Cement
Regulation Number & Product Codes	EMA-21 CFR §872.3275
Proposed Regulatory Class	Class II
Predicate Device Identification	Fuji IX GP K961448 Ketac-Molar Aplicap K960954

Description of Proposed Device

Vitro Molar is a condensable, chemically activated glass ionomer cement, used in restorations of posterior teeth; it is radiopaque and offers good esthetic properties, easy manipulation, fast curing and it can be easily sculpted. It hardens via an acid/base reaction. Vitro Molar is also highly resistant to compression and bending, and has a hard, low-abrasive surface. It is ideal to be used in the atraumatic restorative treatment (ART) technique. Vitro Molar is for permanent cementation.

Indications for Use

- Class I, Class II, Class III and Class V restorations
- Non-bearing Class I and Class II restorations in permanent teeth

- Intermediate restoration for heavy stress situations in Class I and Class II cavities
- Core build up
- Liner

Substantial Equivalence

All of the components of Vitro Molar are found in legally marketed devices. Vitro Molar has the same intended use and similar technical characteristics as the above mentioned predicate devices. The indications for use, materials, form factor, performance and safety characteristics between Vitro Molar and the predicates are the similar.

Conclusion

Based on the information provided in this premarket notification, we can conclude that Vitro Molar is as safe and effective as the predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2013

DFL Industria E Comercio S.A.
C/O Ms. Tara Conrad
Regulatory Affairs Manager
TechLink International
18851 North East 29th Avenue 720
AVENTURA FL 33180

Re: K123826
Trade/Device Name: Vitro Molar
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: December 4, 2012
Received: December 12, 2012

Dear Ms. Conrad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name: Vitro Molar

510(k) Number: (Pending) K123826

Indications for Use:

- Class I, Class II, Class III and Class V restorations
- Non-bearing Class I and Class II restorations in permanent teeth
- Intermediate restoration for heavy stress situations in Class I and Class II cavities
- Core build up
- Liner

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR
Over-The-Counter Use _____ (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEED

Concurrence of CDRH, Office of Device Evaluation
(ODE) Page 1 of 1

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123826